

EPA REGISTRATION NUMBER 56783-2 – VOL. 1

56783-2

2

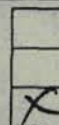


Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460



Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-2	2. EPA Product Manager GEORGE LARocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ECOHEALTH, INC. / MITE ARREST	PM#	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02102 617 742 2400 Fax 617 742 4953 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION JAN 20 2004
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation Notification of Label change relative to PR Notice 2001-6. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make false statements to EPA. I further understand that if this notification is not consistent with the guidance of PR Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Alexander Kovel	Title PRESIDENT	Telephone No. (Include Area Code) 617 742 2400	
2. Signature 		3. Title PRESIDENT	6. Date Application Received (Stamped) DEC 29, 2003
4. Typed Name ALEXANDER KOVEL		5. Date DEC 29, 2003	

ECOHEALTH, INC.

Monday, December 29, 2003

George LaRocca
US Environmental Protection Agency
Pesticide Programs (7504C)
Document Processing Desk (AMEND)
401 M Street S.W.
Washington, DC 20460-0001

Re: 56783-1 (Damminix) and 56783-2 (Mite Arrest)

Dear Mr. LaRocca,

I am sending you under separate cover three different items:

- ✓ • two Notifications, (one for each of the above pesticides, 56783-1 and 56783-2, under PR Notice 2001-6), and
- one Amendment of the label for 56783-2, required by PR Notice 2001-1.

No Amendment for 56783-1 under PR Notice 2001-1 is required, since one was accepted by EPA on January 16, 2002. Unfortunately, at that time I simply overlooked the requirement to file the same First Aid label amendment for 56783-2. Hence, I am enclosing it at this time.

You were very kind to answer my questions on the phone last week, and I hope I have submitted these various applications correctly. If anything else is needed or corrections are required, I will be very pleased to send them immediately.

Thank you very much.

Sincerely,


Alexander Kovel

MITEARREST®

INSECTICIDAL BEDDING FOR LABORATORY RODENTS

For Laboratory, Commercial or Veterinary Use

EPA Reg. No. 56783-2

EPA Est. No. 5693 MA 1

Permethrin impregnated cotton bedding to control mite infestations on laboratory rodents.

ACTIVE INGREDIENT:

+ * Permethrin

INERT INGREDIENTS: -----7.4%
-----92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethyl)2,2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Net Weight 2.5 lbs.

Actual Size

MITEARREST®

INSECTICIDAL BEDDING FOR LABORATORY RODENTS

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

APPLICATION INSTRUCTIONS: Place MITEARREST bedding directly in rodent cage to be treated. Use 2-3 MITEARREST balls per week for each rodent. Avoid wetting the MITEARREST bedding; to prevent cage flooding, care should be taken to place MITEARREST bedding away from the water bottle spout. Replace soiled MITEARREST bedding; it is recommended that fresh MITEARREST bedding be added weekly, at the time when other bedding is changed. Continue using the product for four (4) to six (6) weeks, or until mites or their eggs are no longer present in the fur of rodent. As mite eggs are not affected by this treatment, extended use of the product (until all eggs have hatched or are no longer present) will provide greater long-term control and prevent reinfestation.

STORAGE: Store at room temperature. Do not contaminate water, food or feed by storage.

DISPOSAL

If empty:

Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled:

Call your local solid waste agency or 1-800-234-8425 for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS: Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

NOTE: This product contains a pyrethroid insecticide which the caged animal may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using the product.

U.S. Patent No. 4,662,104

© 2004, ECOHEALTH, INC.

33 MT. VERNON ST. BOSTON, MASSACHUSETTS 02108
617-742-2400

NOTIFICATION

JAN 2 0 2004

Actual Size

Mr. Alexander Kousc
EcoHealth, Inc.
33 Mt. Vernon Street
Boston, MA 02108

JAN 21 2004

Dear Mr. Kousc:

Subject: Label Amendment- PR Notice 2001-1
Mite Arrest
EPA Registration Number 56783-2
Your submission dated December 29, 2003

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

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U.S. Patent No. 4,662,104

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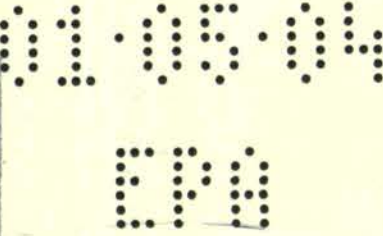
33 MT. VERNON ST. BOSTON, MASSACHUSETTS 02108
617-742-2400

Actual Size

ACCEPTED

JAN 21 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 56783-2





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-2	2. EPA Product Manager GEORGE LARocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ECOHEALTH, INC. / MITE ARREST	PM#	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108 617 742 2400 Fax 617 742 4953	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

AS PER PR NOTICE 2001-1 RE FIRST AID STATEMENT

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
*Notification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
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Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name ALEXANDER FOVEL	Title PRESIDENT	Telephone No. (Include Area Code) 617 742 2400
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped)
2. Signature Alexander Fovel	3. Title PRESIDENT	
4. Typed Name ALEXANDER FOVEL	5. Date DEC 27, 2003	

ECOHEALTH, INC.

Monday, December 29, 2003

George LaRocca
US Environmental Protection Agency
Pesticide Programs (7504C)
Document Processing Desk (AMEND)
401 M Street S.W.
Washington, DC 20460-0001

Re: 56783-1 (Damminix) and 56783-2 (Mite Arrest)

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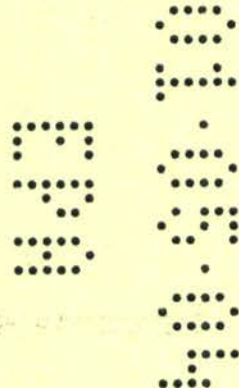
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You were very kind to answer my questions on the phone last week, and I hope I have submitted these various applications correctly. If anything else is needed or corrections are required, I will be very pleased to send them immediately.

Thank you very much.

Sincerely,

Alexander Kovel



Reg Number: Reg. Type: Status:
 Name: [<View Registration Details>](#)

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

- ...Decisions...
- [-] D: 337774; 56783-2;300;LABEL REVISION;NO DATA REQUIRED
- [-] S: 751932 1/5/04, Amendment, 56783
- [+] D: 306284; 56783-2;455;ENFORCEMENT CASE
- [+] D: 120126; 56783-2;300;LABEL REVISION;NO DATA REQUIRED
- [+] D: 120125; 56783-2;455;ENFORCEMENT CASE
- [+] D: 120124; 56783-2;305;DATA REQUIRED;TECHNICAL
- [+] D: 120123; 56783-2;175;NEW REGISTRATION;NO DATA REQUIRED
- [-] Data Requirements

S: Reg #:

Submission Type:

Resubmission?: ☐ Yes ☒ No

Decision #:

Submitter Company:

Application Date:

OPP Received Date: Date Sent to Risk manager:

Studies Included?: ☐ Yes ☒ No Fast Track?: ☒ Yes ☐ No

Form A Signed?: ☐ Yes ☐ No ☒ None Date:

Form B Signed?: ☐ Yes ☐ No ☒ None Date:

Reviewer:

Received DT: Editable Due DT:

Admin Due DT: Response:

Priority Weight: Priority Points:

Comments:

300-10

G. LAIOCCA

1-8-04

Receipt for Section 3

S: 751932

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Amendment



Company: 56783 COHEALTH, INC. V



Risk Manager: Registration Division, Risk Management Team 13

Product #: 56783-2 Product Name: MITE ARREST

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 29-Dec-2003  OPP Rec'd Date: 05-Jan-2004 

Front End Date: 07-Jan-2004  Risk Manager Send Date: 07-Jan-2004 

Fast Track: ☐ Studies: ☐ New Ingredient: ☐

Receipt Description:

2007-1

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 7, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ALEXANDER KOVEL
ECOHEALTH, INC.
33 MT. VERNON ST.
BOSTON, MA 02108

PRODUCT NAME: MITE ARREST
COMPANY NAME: ECOHEALTH, INC.
EPA FILE SYMBOL: 56783-2
EPA RECEIPT DATE: 01/05/04

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-6100.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. White", is written below the "Sincerely," text.

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 17 1993

300-544086
38/6

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis,

Subject: Compliance with Labeling Requirements in PR notice 93-3
Your Letter Dated April 26, 1993

The above referenced letter to Lawrence Culleen was forwarded to me for response. In your letter you indicate that you intend to comply with the labeling changes outlined in PR notice 93-3 concerning the statement prohibiting application to water but request an extension from the April 21, 1994 deadline. In order for us to consider such a request, you must indicate an estimated amount of time needed to comply and/or an agenda for implementing the required changes.

Please feel free to contact me at (703) 305-6100 if you have any questions.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

CONCURRENCES

SYMBOL							
SURNAME	TML						
DATE	5/14/93						13

577
IRB - please respond directly as appropriate.
ECOHEALTH INC.

The Makers of DAMMINIX . . . for control of Lyme Disease carryin

George
Please
Respond
Susan

April 26, 1993

Mr. Lawrence E. Culleen
Acting Director
Registration Division (H 7505 C)
Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Culleen:

We have received PR notice 93-3 "Labeling Statement Prohibiting Application to Water" and intend to comply as quickly as possible but request an extension from the proposed April 21, 1994 deadline. As I explained to Jeff Kempter, EcoHealth is a small company (less than \$1 million in sales). In order to buy packaging and other labeled components at affordable prices, we purchase several year's supply at a time. Even then, the unit cost of our labeling (box and tubes) is over \$3.00 compared to 3-5¢ for a typical pesticide label. The financial cost of complying with the proposed 1994 deadline would be disastrous for our company, and for the thousands of people who depend on Damminix for protection from Lyme disease carrying ticks.

Damminix has much less toxicity and impact on the environment than other tick control methods. In addition, the active ingredient (permethrin @ <1/2 ounce A.I./acre) is impregnated in the cotton fiber and nearly insoluble in water.

If Damminix is no longer available, homeowners will be forced to resort to compounds that are used at significantly higher rates and have much more environmental impact. If you can give EcoHealth some flexibility on the deadline, we will make the desired changes as quickly as we are able while continuing to provide homeowners with the least toxic approach to deer tick control. Please contact me regarding an extension to the deadline. Thank you for your consideration.

Sincerely,

Fred DeFinis

Fred DeFinis
President

CERTIFIED MAIL #655 440 088
RETURN RECEIPT REQUESTED

RECEIVED
5/4/93
REGISTRATION DIVISION
H-7505C
RD-7790

10/3/92
Chow

652BB

2-0658
12/5/91

DP BARCODE: D171969

CASE: 027678
SUBMISSION: S407829

DATA PACKAGE RECORD
BEAN SHEET

DATE: 12/04/91
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
CHEMICALS: ~~109701~~ Permethrin

07.4000%

ID#: 056783-00002 MITE ARREST
COMPANY: 056783 ECOHEALTH, INC.
PRODUCT MANAGER: 13 GEORGE LARocca 703-305-6100 ROOM: CM2 202
PM TEAM REVIEWER: THERESA LEMASTER 703-305-5418 ROOM: CM2 204
RECEIVED DATE: 11/22/91 DUE OUT DATE: 02/20/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 171969 EXPEDITE: N DATE SENT: 12/04/91 DATE RET.: / /
CHEMICAL: 109701 Permethrin
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 01/18/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT
DIV : HED	/	/	/	/
BRAN: SACB	/	/	/	/
SECT: RS	/	/	/	/
REVR :	/	/	/	/
CONTR:	/	/	/	/

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: FLORA CHOW

PLEASE COMMENT ON PROPOSED LABEL AMENDMENT TO INCLUDE
"HOMEOWNER" USE OF THIS PRODUCT.

LAST HED REVIEW (APR 19, 1990 - COPY ENCLOSED) WAS MADE IN
REFERENCE TO LABEL WHICH LIMITED USE OF THIS PRODUCT TO
"COMMERCIAL/VETERINARY USE ONLY" (COPY ENCLOSED).

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT 03 1992

MEMORANDUM

SUBJECT: Risk Assessment for Mite Arrest

TO: Theresa LeMaster/George LaRocca, PM 13
Registration Division (H7505C)

FROM: Flora Chow, Acting Section Head *Flora Chow 30 Sept 92*
Reregistration Section
Chemical Coordination Branch
Health Effects Division (H7509C)

THROUGH: Esther Saito, Acting Chief *ABK*
Chemical Coordination Branch
Health Effects Division (H7509C)

HED Project No.: 2-0658
Submission No.: S407829
Caswell No.: 652BB

A revised exposure assessment for the product Mite Arrest (J. Tice. Exposure Assessment for Mite Arrest. Memorandum to G. LaRocca. 17 July 1992) has been conducted by OREB. This assessment supersedes a memo dated 17 March 1992 on the same subject. A risk assessment based on this new information is detailed below.

CONCLUSION

- o The HED Peer Review Committee on Carcinogenicity classified permethrin as a Group C_q carcinogen; the estimate of unit risk, Q_1^* , is 1.8×10^{-2} (mg/kg/day)⁻¹.
- o The extra cancer risk to consumers (generally children) who use the product in animal cages is estimated at 5×10^{-7} .



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at least 75% recycled fiber

DISCUSSION

The revised exposure assessment from OREB contains the following changes:

- (1) A 0.5 oz container of Mite Arrest cotton balls contains 0.037 g active ingredient. (The former memo gave an amount of 2.8 g active ingredient per 0.5 oz container.)
- (2) The amount of permethrin migrating to the skin from the cotton balls is assumed to be 4%; this is the amount found to migrate to skin from permethrin-treated cotton battle dress uniforms. (The former memo assumes 100% migration.)

Based on this information, exposure to permethrin is expected to be 0.139 mg/kg/year for a 35 kg child.

Risk characterization. Estimates of the extra cancer risk is calculated from the following equation:

$$\text{Extra risk} = \text{LADD} \times Q_1^*$$

where:

$$\text{LADD} = \frac{0.139 \text{ mg/kg/yr}}{365 \text{ days}} \times \frac{70}{70} \times \text{Absorption}$$

Dermal absorption = 7% This is based on (1) a rabbit dermal absorption study where 30 to 70% of permethrin was found to be absorbed, and (2) rabbit skin is 10 to 15 times more permeable than human skin.

and $Q_1^* = 1.84 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$

The extra risk to a child using the permethrin containing Mite Arrest is calculated to be 5×10^{-7} .

cc: M. Copley
J. Doherty
J. Tice

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 22 1997

306/5414655
~~305/5407827~~
 17/2
 38/

Mr. Fred DeFinis
 President
 EcoHealth, Inc.
 110 Broad Street
 Boston, MA 02110

Dear Mr. DeFinis,

Subject: Amendment - Homeowner Use Labeling
 Mite Arrest
 EPA Registration Number 56783-2
 Your Submissions Dated November 12, 1991
 and March 16, 1992

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

On the commercial label delete the user limitation "For Laboratory, Commercial or Veterinary Use Only" since the product can also be used in the home.

We have reevaluated the inhalation and dermal exposure to the homeowner from handling the product and having the product in the home and conclude that such exposure is comparable to other accepted uses of permethrin in the home. However, to minimize any potential exposure in the home environment, we strongly encourage you to modify the shape or color of the product so that it does not so closely resemble cotton balls used for non-pesticide purposes.

Submit five copies of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
 Product Manager (13)
 Insecticide-Rodenticide Branch
 Registration Division (H7505C)

CONCURRENCES							
SYMBOL	Enclosure						
SURNAME	<i>me</i>						
DATE	<i>6/18/92</i>						

MITEARREST®

INSECTICIDAL BEDDING FOR RODENTS



FOR HOME PET USE

EPA Reg. No. 56783-2 EPA Est. No. 5693 MA 1
Permethrin impregnated cotton bedding to
control mite infestations on rodents.

ACTIVE INGREDIENTS:
+ permethrin.....7.4%
INERT INGREDIENTS.....92.6%
Total 100.0%
+(3-phenoxyphenyl methyl (+/-) cis/trans 3-(2-
dichloroethenyl)-2,2-dimethyl cyclopropano-carboxylate
*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

KEEP OUT OF REACH OF CHILDREN CAUTION

Statement of Practical Treatment
IF SWALLOWED - Contact a physician or Poison Control
Center immediately.
IF ON SKIN - Remove contaminated clothing and wash
affected areas with plenty of soap and water.
IF IN EYES - Flush eyes with plenty of water. Call a physi-
cian if irritation persists.
See additional precautionary statements

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a
manner inconsistent with its labeling.

APPLICATION INSTRUCTIONS

Place MITEARREST bedding directly in rodent cage to be
treated. Use 2-3 MITEARREST balls per week for each
rodent. Avoid wetting the MITEARREST bedding; to pre-
vent cage flooding, care should be taken to place
MITEARREST bedding away from the water bottle spout.
Replace soiled MITEARREST bedding; It is recommended
that fresh MITEARREST bedding be added weekly, at the
time when other bedding is changed. Continue using
the product for four to six weeks, or until mites or their
eggs are no longer present in the fur of rodent. As mite
eggs are not affected by this treatment, extended use of
the product (until all eggs have hatched or are no longer
present) will provide greater long-term control and pre-
vent reinfestation.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water,
food or feed by storage or disposal. Unused or soiled
MITEARREST bedding is biodegradable and may be dis-
posed of with other bedding (such as wood chips, shav-
ings, etc.) or refuse. Soiled MITEARREST bedding may be
autoclaved or incinerated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to
skin may cause dermal irritation or tingling. Wash thor-
oughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contami-
nate water by disposal.

U.S. Patent No. 4,662,104

EcoHealth, Inc., (617) 742-2400
110 Broad Street, Boston, MA 02110
Net. weight .5 oz.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN 22 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

56783-2

To: Alex Kaul 4-4-96
From: John Helant
7033055419
108

ACTIVITY REPORT

TRANSMISSION OK

TX/RX NO.	5834
CONNECTION TEL	916173506260
CONNECTION ID	G3
START TIME	07/22 12:41
USAGE TIME	01'25
PAGES	2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FACSIMILE REQUEST / COVER SHEET

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SEND FAX TO:

NAME: Fred De Finis
OF: Ecohealth
FAX PHONE NUMBER: (617) 350-6260
OFFICE PHONE NUMBER: (617) 742-2400

FROM:

NAME: Theresa LeMaster
DIVISION/BRANCH: RD / IRB
OFFICE PHONE NUMBER: (703) 305-5418
OFFICE ROOM NUMBER: _____
MAIL CODE: _____
DATE: 7/22/92 TIME: _____
NUMBER OF PAGES (including cover sheet): _____

SPECIAL MESSAGE:



Printed on Recycled Paper

DP BARCODE: D171969

652BB

2-0658
12/5/91

CASE: 027678
SUBMISSION: S407829

DATA PACKAGE RECORD
BEAN SHEET

DATE: 12/04/91
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
CHEMICALS: 109701 Permethrin 07.4000%

ID#: 056783-00002 MITE ARREST
COMPANY: 056783 ECOHEALTH, INC.
PRODUCT MANAGER: 13 GEORGE LARocca 703-305-6100 ROOM: CM2 202
PM TEAM REVIEWER: THERESA LEMASTER 703-305-5418 ROOM: CM2 204
RECEIVED DATE: 11/22/91 DUE OUT DATE: 02/20/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 171969 EXPEDITE: N DATE SENT: 12/04/91 DATE RET.: / /
CHEMICAL: 109701 Permethrin
DP TYPE: 001 Submission Related Data Package
MIN DUE DATE: 01/18/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT
DIV : HED	/	/	/	/
BRAN: SACB	/	/	/	/
SECT: RS	/	/	/	/
REVR :	/	/	/	/
CONTR:	/	/	/	/

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: FLORA CHOW

PLEASE COMMENT ON PROPOSED LABEL AMENDMENT TO INCLUDE
"HOMEOWNER" USE OF THIS PRODUCT.

LAST HED REVIEW (APR 19, 1990 - COPY ENCLOSED) WAS MADE IN
REFERENCE TO LABEL WHICH LIMITED USE OF THIS PRODUCT TO
"COMMERCIAL/VETERINARY USE ONLY" (COPY ENCLOSED).

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 17 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: EXPOSURE ASSESSMENT FOR MITE ARREST, EPA REG # 56783-2

TO: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: John Tice, Acting Head *John Tice*
Special Review and Registration Section I
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

THRU: Larry Dorsey, Acting Chief *Larry Dorsey 6/17/92*
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below, the OREB review of:

HED Project No.: 2-0658

Caswell No.: 652 BB

Pesticide Chemical Code: 109701

EPA Reg. No.: 56783-2

EPA MRID No.: NONE

Barcode: D171969

Review Time: 2.5 DAYS

Referred to SACB for risk assessment.



NOTE: This review supersedes/replaces a prior memo dated March 17, 1992. The old memo was found to be inaccurate and is being replaced by this memo. This memo further refines the exposure estimates for children handling Mite Arrest.

I. INTRODUCTION:

EcoHealth, Inc. requested a label amendment to add "Homeowner Use" to the label of their product Mite Arrest. The home owner product will be packaged in 0.5 oz. containers. Mite Arrest is a permethrin-impregnated cotton ball that is placed into pet-rodent cages to control mites. A 0.5 oz container contains 0.037 g ai contained on approximately 47 balls. The use directions suggest using 2 - 3 balls per rodent per week in the cage litter. If the total amount of ai in the container is 0.037 g ai and there are 47 cotton balls in each can the amount of permethrin ai on each ball is 0.00078 g ai or 0.78 mg ai per ball.

OREB has been asked to evaluate the inhalation and dermal exposure to the homeowner from handling the product and from having the product in the home.

II. CONCLUSIONS:

OREB has evaluated the exposure to home owner and finds the exposure from the Mite Arrest use to control mites in pet-rodent cages to be comparable to other accepted uses of permethrin.

III. DISCUSSION:

Exposures to permethrin associated with Mite Arrest are estimated to be comparable to exposures associated with other permethrin uses¹. Assuming a 9 - 12 year old (35 kg) child changes one cage on a weekly basis, handling 3 cotton balls each week, and being exposed to 100% of the permethrin in the balls. The daily exposure would be:

$3 * 0.78 \text{ mg AI} = 2.3 \text{ mg AI} * 52 \text{ weeks} = 121.6 \text{ mg ai exposure per year.}$

¹ Registration of Permethrin for Military Uses (HED Project # 9-1356) Memo to G. LaRocca, PM 15, Dated 31 July 1989 estimated an exposure of 0.0056 mg/kg/day or 2.0 mg/kg/yr uncorrected for dermal exposure. Permanone Tick Repellent Exposure Assessment for civilian Uses (HED Project #9-2158), which yielded a child exposure of 2.2 mg/kg/day and 200 mg/kg/yr uncorrected for dermal exposure.

Assuming that 4 % of the permethrin migrated from the cotton balls to the skin² the yearly exposure would be:

$$121.6 \text{ mg/yr} * .04 = 4.86 \text{ mg ai/yr exposure.}$$

Assuming a 35 kg child changing the cage, the yearly exposure would be $4.86 \text{ mg ai} \div 35 \text{ kg bw} = 0.139 \text{ mg/kg/yr}$.

The daily exposure is then calculated as $0.139 \text{ mg/kg/yr} \div 365 \text{ days/yr}$ or $0.00038 \text{ mg/kg/day}$.

These exposures are not corrected for dermal absorption.

The anticipated dermal exposure is comparable to the anticipated exposures to other approved uses of permethrin.

Inhalation exposure associated with handling 3 cotton balls, collectively containing 2.3 mg of permethrin, is negligible compared to the inhalation exposure associated with the military use. The military use applied 0.8 grams of product 3 - 4 times a year to clothing which was then placed in contact with the body for a year.

cc: Circulation
Correspondence File
Chemical File
Flora Chow, SACB
John Doherty, (TB-1)

² Migration of Permethrin from Impregnated Military Fabrics as Measured in Rabbits, Dated 11/30/88; MRID #407668-13.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Returned to OREB 4/1/92

MAR 17 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: EXPOSURE ASSESSMENT FOR MITE ARREST, EPA REG # 56783-2

TO: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C) *3/17/92*

FROM: John Tice, Biologist
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

THRU: Mark I. Dow, Ph.D., Section Head *Mark I. Dow*
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Charles L. Trichilo, Ph.D., Chief
Occupational and Residential Exposure Branch
Health Effects Division (H7509C) *CT*

Please find below, the OREB review of:

HED Project No.: 2-0658
Caswell No.: 652 BB
Pesticide Chemical Code: 109701
EPA Reg. No.: 56783-2
EPA MRID No.:
Barcode: D171969
Review Time: 1.5 DAYS



I. INTRODUCTION:

EcoHealth, Inc. requested a label amendment to add "Homeowner Use" to the label of their product Mite Arrest. The home owner product will be packaged in 0.5 oz. containers. Mite Arrest is a permethrin-impregnated cotton ball that is placed into pet-rodent cages to control pest mites. Each cotton ball, weighs approximately 0.3 grams, and contains approximately 0.06 grams of permethrin. If the total package weighs 0.5 oz (14.1 grams). there are approximately 47 cotton balls per container. The total permethrin concentration in a 0.5 oz container would then be approximately 2.8 grams of active ingredient.

OREB has been asked to evaluate the inhalation and dermal exposure to the homeowner from handling the product and from having the product in the home.

II. CONCLUSIONS:

OREB has evaluated the exposure to home owner and finds the exposure from the Mite Arrest use to control mites in pet-rodent cages to be significantly less than other accepted uses of permethrin.

III. DISCUSSION:

Exposures to permethrin associated with Mite Arrest are estimated to be lower than other permethrin uses¹. Assuming a 9 - 12 year old (35 kg) child changes one cage on a weekly basis, handling 3 cotton balls each week, and being exposed to 100% of the permethrin in the balls. The daily exposure would be:

$$3 \times 0.06 \text{ g AI} = 0.18 \text{ g AI} \times 52 \text{ weeks} = 9.3 \text{ g/yr exposure.}$$

$$9.3 \text{ g} / 35 \text{ kg person} = 26.5 \text{ mg/kg/yr exposure}$$

Assuming 70% dermal absorption²:

$$26.5 \text{ mg/kg/yr} \times 0.70 = 0.186 \text{ mg/kg/yr exposure or } .00050 \text{ mg/kg/day.}$$

¹ Registration of Permethrin for Military Uses (HED Project # 9-1356) Memo to G. LaRocca, PM 15, Dated 31 July 1989.

² Figure taken from Toxicology summary derived from U.S. Army Dermal absorption study on rabbits.

This dermal exposure is an order of magnitude less than the exposure calculated for military use of Permethrin on Battle Dress Uniforms. The exposure to homeowners is estimated to be considerably less. With normal handling, it is impossible to come in contact with all the permethrin impregnated in the cotton. Additionally, all the permethrin that is contacted, is not expected to adhere to the skin. Since there are no data for permethrin adhering to the skin, assuming 100% contact and adhesion provides a very conservative estimate of exposure.

Inhalation exposure associated with handling 3 cotton balls, collectively containing 0.18 grams of permethrin, is negligible compared to the inhalation exposure associated with the military use. The military use applied 0.8 grams of product 3 - 4 times a year to clothing which was then placed in contact with the body for a year.

cc: Circulation
Correspondence File
Chemical File
Flora Chow, SACB
John Doherty, (TB-1)

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . *for control of Lyme Disease carrying ticks.*

VIA FAX

Ms. Theresa LeMaster
Registration Division (H7505C)
Environmental Protection Agency
Crystal Mall, Building 2
Arlington, VA 22202

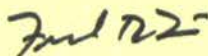
Subject: Mite Arrest
EPA Reg. No.: 56783-2

Dear Ms. LeMaster:

As we discussed, the home use version of Mite Arrest will be packaged in a size just under 1/2 ounce, and will be under a separate label "split" from our laboratory product. Total active ingredient will be under .037 oz. for the entire container. Further, the active is bound to the cotton in manufacturing and all volatile compounds driven off in the drying process.

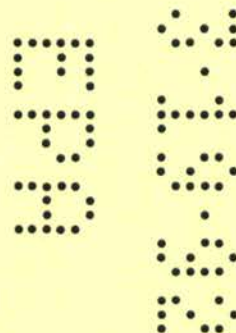
Three labels are enclosed for your review.

Sincerely,



Fred DeFinis
President

/enc.



ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

VIA FAX

March 27, 1992

Ms. Theresa LeMaster
Environmental Protection Agency
Crystal Mall, Bldg. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

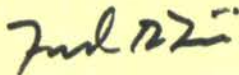
RE: Product Name: Mite Arrest
EPA Registration No.: 56783-2

Dear Ms. LeMaster:

Please call me regarding our pending label amendment (EPA #56783-2). I would like to know if everything is progressing smoothly and when we may expect to receive approval.

Thank you for your help.

Sincerely,



Fred DeFinis
President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 18 1992

4555419812
38/5MEMORANDUM

SUBJECT: ENFORCEMENT CASE REVIEW REQUEST
OCM/ECR LOG NO. 92-I-09
INSPECTION NO. PJR-9222
Registrant - Ecohealth, Inc.
EPA Reg. No. 56783-2 (Mitearrest)

FROM: George LaRocca, Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

TO: Mary McDonnell, HQ Regional Coordinator
Case Support Branch
Compliance Division (EN-342)

As requested, we have reviewed the labeling of the sample product against the last accepted label and determined that directions for use including other label text are acceptable.

cc: Herb Harrison, Chief
Insecticide-Rodenticide Branch

CONCURRENCES

SYMBOL								
SURNAME	JML							
DATE	6/17/92							

Rec'd
3/18/92
Rfr

✓(Team 13) #56783-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

Date: 3/17/92

TRANSMITTAL SHEET:

SUBJECT: Enforcement Case Review Request

OCM/ECR LOG NUMBER : 92-I-09

INSPECTION NUMBER : PJR-9222

FROM: Case Support Branch, Compliance Division, OCM-OPTS

TO: ☐ _____
Disinfectant Branch
☐ _____
Herbicide - Fungicide Branch
☒ _____
Insecticide - Rodenticide Branch
☐ _____
Registration Support & Emergency Response

The attached inspection file requires technical evaluation of the following Product element/s:

<input type="checkbox"/> Registration	<input type="checkbox"/> Content	<input type="checkbox"/> Formulation
<input type="checkbox"/> (Device ?)	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Toxicity
<input checked="" type="checkbox"/> Labeling	<input type="checkbox"/> Claims	<input type="checkbox"/> Advertising
<input type="checkbox"/> Packaging	<input type="checkbox"/> Other _____	

Mary McDonald
Case Officer

This review is requested because:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION I

J.F. KENNEDY FEDERAL BUILDING, BOSTON, MASSACHUSETTS 02203-2211

Date: 3/12/92

MEMORANDUM

SUBJECT: Request for Enforcement Case Review:
Sample No. Doc. Sample PSR 9222 2/5/92
Registrant: Ecokem, Inc.
EPA Reg. No. 56783-2

FROM: Sharlene Speizer / Bob Kslyjian
Regional Case Development Officer

TO: Mary McDonnell
HQ Regional Coordinator

This jacket is being submitted for the following enforcement case review:

<u>X</u>	Labeling
<u>X</u>	Copy of latest accepted label
<u>X</u>	Full Review and comment on differences in comparison to label accepted _____, specifically as highlighted on the accepted sample label.
_____	Registration status
_____	Claims
_____	Device
_____	Other _____

Specific comments/details regarding this request are discussed below:

Application Instructions as accepted by HQS?

Please contact me at FTS-835-9129 if you have any questions.

Attachment: Sample Jacket /X/

U.S. ENVIRONMENTAL PROTECTION AGENCY COLLECTION REPORT				1. TYPE SAMPLE P.E.I.	2. SAMPLE NO. "PJR 9222 2-5-92"
3. DATE COLLECT 2-5-92	4. PROJ CODE M-1-	5. REGION NO. I	6. INSP NO. 2018	7. REGISTRATION NO. 56783-2	8. ESTABLISHMENT NO. 5693-MA-1
9. DATE(S) SHIPPED n/a				10. FLAG Region I request	
11. PRODUCT IDENTIFICATION (Name, Brand, Q.C. Statement, Active Ingredients, Firm Name and Address, etc.) Cardboard box with the label printed on it "MITEARREST Insecticidal bedding for laboratory rodents: Active ingredients Permethrin 7.4%***Eco Health, Incorporated, 110 Broad Street, Boston, MA. 02110***NET Weight .5 lbs.***"					
12a. PRODUCER ESTABLISHMENT SHIELD PACKAGING COMPANY, INC.					
b. STREET ADDRESS P.O.Box 729 Peter St.			c. CITY Webster	d. STATE MA	e. ZIP CODE 01570
13a. SHIPPER same as above					
b. STREET ADDRESS			c. CITY	d. STATE	e. ZIP CODE
14a. DEALER n/a					
b. STREET ADDRESS			c. CITY	d. STATE	e. ZIP CODE
15. RECORDS AND SAMPLE SENT TO (Specify location)					
a. ORIGINAL RECORDS EPA Region I offices			b. PRODUCING REGION COPY Region I	c. SAMPLE PJR 9222 2-5-92	
d. SAMPLE DELIVERED TO: EPA Region I			e. DATE	f. B/L NO. n/a	
16. LOT OR CODE NOS. NA					
17. AMOUNT BEFORE SAMPLING 113					
18. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION Empty box was collected from a stack of boxes that were to be used filled on the next manufacturing date, the original label is on file at MDFA.					
19. SAMPLE PREPARED IN THE FOLLOWING MANNER Sample(s) identified as "PJR 9222 2-5-92" <i>Paul J Ricco</i> polybagged, and sealed with M.D.F.A. seals, as "PJR 9222 2-5-92", Paul J. Ricco.					
20. RELATED SAMPLES COLLECTED FROM SAME SHIPMENT OR AT THE SAME PRODUCER ESTABLISHMENT "PJR 9205/9224 2-5-92"					
21. REASON FOR COLLECTION Region I request					
22. NOTICE OF INSPECTION ISSUED			23. RECEIPT FOR SAMPLES ISSUED		
24. REMARKS The labels collected have been compared to the samples that have been packaged, labeled, and released for shipment, and have been found to be identical, the sample came from a previously unopened case.					
25. SAMPLE COST \$ n/a	C	V	B	26. COLLECTION STA Boston, MA	27. COLLECTOR'S NAME (Type) AND SIGNATURE Paul J. Ricco <i>Paul J Ricco</i>



U. S. ENVIRONMENTAL PROTECTION AGENCY

NOTICE OF INSPECTION

ADDRESS (EPA Regional Office)

Pesticide Bureau
100 Cambridge Street
Boston, MA 02202

DATE

2-5-92

HOUR

9:00

A.M.
P.M.

NAME OF INDIVIDUAL

Robert L. McCollum

TITLE

Technical Director

FIRM NAME

Shield Packaging Company
Inc

FIRM ADDRESS (Number, Street, City, State and Zip Code)

Peter Street
P.O. Box 729
Webster, MA 01570
508-949-0900

SIGNATURE OF EPA EMPLOYEE

Paul J. Muen

TITLE

Sup Inspector

REASON FOR INSPECTION

☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING SAMPLES OF ANY PESTICIDES OR DEVICES PACKAGED, LABELED, AND RELEASED FOR SHIPMENT, AND SAMPLES OF ANY CONTAINERS OR LABELING FOR SUCH PESTICIDES OR DEVICES, IN PLACES WHERE PESTICIDES OR DEVICES ARE HELD FOR DISTRIBUTION OR SALE (Sec. 9(a) and 12(a)(2)(B)).☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN SECTION 8 AND 40 CFR PART 169. (Sec. 8 and 12(a)(2)(B)).

VIOLATION SUSPECTED:

possible production and distribution
of pesticides which have been cancelled

Section 8, 9(a) and 12(a)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 et seq.) are quoted on the reverse of this form.



U.S. ENVIRONMENTAL PROTECTION AGENCY

RECEIPT FOR SAMPLES

ADDRESS (EPA Regional Office)

Postoffice Bureau
100 Cambridge St
Boston, MA 02202

DATE

2-5-92

NAME OF INDIVIDUAL

ROBERT L. M. Collum

TITLE

Technical Director

FIRM NAME

SHIELD PACKAGING COMPANY, INC.
508-949-0900

ADDRESS (Street, City, State and Zip Code)

PETER STREET
WEBSTER, MA 01570

SAMPLE NUMBERS

PH 9222/ PR 9221 2-5-92 PH

SAMPLES COLLECTED (Describe fully, List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.)

The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged pursuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form.

Doc. Mikeant 51bs
Label box

EPA Reg 5679-2

EPA FST 5693-MA-1

Doc Indoor fogger 507
Label

EPA Reg 5693-61-3546

EPA FST 5693-MA-1

Doc Home in garden 17
Label

EPA Reg 5693-46-3546

EPA FST 5693-MA-1

ACKNOWLEDGMENT OF PRODUCER/REGISTRANT

The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.

SIGNATURE (Owner, Operator, or Agent)

TITLE (Owner, Operator or Agent)

☒ DUPLICATE SAMPLES
REQUESTED AND PROVIDED☐ DUPLICATE SAMPLES
NOT REQUESTED

SAMPLES WERE

☐ PURCHASED

N/C

☐ BORROWED

AMOUNT PAID FOR SAMPLES

\$

☐ CASH☐ VOUCHER☐ TO BE BILLED

NAME OF COLLECTOR (Print or type)

PAUL J. RICO

TITLE OF COLLECTOR

INSPECTOR

SIGNATURE OF COLLECTOR

ESTABLISHMENT INSPECTION REPORT				1. VISIT
2. REGION NO. 01/MA		3. INSPECTOR NO. 2018		4. DATE OF VISIT 2-5-92
				5. ESTAB. REGISTRATION NO. 5693-MA-001
6. ESTABLISHMENT NAME AND ADDRESS (Including Street, city, state, ZIP code, county and phone number) Shield Packaging Company, Inc. Peter Street P.O. Box 729 Webster, MA 01570 (508) 949-0900			7. RELATED FIRMS Shield Packaging Company, Inc. 1565 G Street Chino, CA 91710	
8. TYPE OF ESTABLISHMENT Producer		9. TYPE OF OWNERSHIP Corporation		10a. TOTAL ANNUAL SALES 6 - 7million
				10b. PERCENT PESTICIDES 1 - 2%
11. NAMES AND TITLES OF OF PRINCIPAL OFFICERS, PARTNERS OR OWNERS George Bates , President Lou Scagzie , Executive Vice President Bruce Simpson , Vice President Operations				
12. PERSONS INTERVIEWED (Give name, title, phone number and responsibility) Robert McCollum - Technical Manager Ian Copland - Administrative Manager				
13a. PHYSICAL SAMPLES COLLECTED		13b. DOCUMENTARY SAMPLES		13c. LABELS REVIEWED WITHOUT SAMPLES
EPA REGISTRATION NO.	SAMPLE NO.	EPA REGISTRATION NO.	SAMPLE NO.	EPA REGISTRATION NO.
56783-1	PJR 9205	3546-27	PJR 9210	572-321
3546-27	PJR 9206	5693-46-3546	PJR 9211	8590-598
546-28	PJR 9207	4816-508-3546	PJR 9212	8590-479
7176-12	PJR 9208	5693-61-3546	PJR 9213	2347-9
2347-9	PJR 9209	5693-61-3546	PJR 9214	2398-7
		5693-76-3546	PJR 9215	2398-7
		5693-46-3546	PJR 9216	
14. REMARKS <u>DOCUMENTARY SAMPLES (Continued)</u> 3546-27 PJR 9217 5693-61 PJR 9223 5693-46 PJR 9218 5693-46 PJR 9224 3546-27 PJR 9219 4186-508 PJR 9220 7176-6 PJR 9221 56783-2 PJR 9222				
15. SIGNATURE OF INSPECTOR			16. INSPECTOR'S STATION Boston, MA <i>Paul Miller</i>	

MITEARREST®

INSECTICIDAL BEDDING FOR LABORATORY RODENTS

For Laboratory, Commercial or Veterinary Use

EPA Reg. No. 56783-2

EPA Est. No. 5693 MA 1

Permethrin impregnated cotton bedding to control mite infestations on laboratory rodents.

ACTIVE INGREDIENTS:

+* permethrin.....7.4%

INERT INGREDIENTS:.....92.6%

Total 100.0%

+(3-phenoxyphenyl methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropane-carboxylate

*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF SWALLOWED - Contact a physician or Poison Control Center immediately.

IF ON SKIN - Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES - Flush eyes with plenty of water. Call a physician if irritation persists.

See additional precautionary statements

Net Weight .5 lbs.

INSECTICIDAL

MITEARREST®

INSECTICIDAL BEDDING FOR LABORATORY RODENTS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

APPLICATION INSTRUCTIONS

Place MITEARREST bedding directly in rodent cage to be treated. Use 2-3 MITEARREST balls per week for each rodent. Avoid wetting the MITEARREST bedding; to prevent cage flooding, care should be taken to place MITEARREST bedding away from the water bottle spout. Replace soiled MITEARREST bedding; it is recommended that fresh MITEARREST bedding be added weekly, at the time when other bedding is changed. Continue using the product for four to six weeks, or until mites or their eggs are no longer present in the fur of rodent. As mite eggs are not affected by this treatment, extended use of the product (until all eggs have hatched or are no longer present) will provide greater long-term control and prevent reinfestation.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage or disposal. Unused or soiled MITEARREST bedding is biodegradable and may be disposed of with other bedding (such as wood chips, shavings, etc.) or refuse. Soiled MITEARREST bedding may be autoclaved or incinerated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to skin may cause dermal irritation or tingling. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contaminate water by disposal.

NOTE:

This product contains a pyrethroid insecticide which the caged animal may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using this product.

U.S. Patent No. 4,662,104

EcoHealth, Inc. (617) 742-2400
110 Broad Street, Boston, MA 02110

For Laboratory, Co

Doc sample T

MITEA

INSECTICIDAL BEDDING

EcoHealth, Inc.

110 Broad Street
Boston, MA 02110

617/742-2400
Fax/350-6260

Fax Cover Letter

Date:	3-16 92
Time:	2:35

To/Company:	EPA	To/Fax#:	
Attention:	Ms Theresa LeMaster		703 305 6596
From:	Fred Detinis		

Including this cover sheet, there are 3 pages in this transmission.

Attached Documents:

Comments:

These are transmitted as checked:

<input type="checkbox"/> As requested	<input type="checkbox"/> For your use	<input type="checkbox"/> For approval	<input type="checkbox"/> For review and comment	<input type="checkbox"/> No reply necessary
---------------------------------------	---------------------------------------	---------------------------------------	---	---

Our Fax # is 617/350-6260

If you have any problems or questions,
please call 617/742-2400

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

VIA FAX

Ms. Theresa LeMaster
Registration Division (117505C)
Environmental Protection Agency
Crystal Mall, Building 2
Arlington, VA 22202

Subject: Mite Arrest
EPA Reg. No.: 56783-2

Dear Ms. LeMaster:

As we discussed, the home use version of Mite Arrest will be packaged in a size just under 1/2 ounce, and will be under a separate label "split" from our laboratory product. Total active ingredient will be under .037 oz. for the entire container. Further, the active is bound to the cotton in manufacturing and all volatile compounds driven off in the drying process.

Three labels are enclosed for your review.

Sincerely,

Fred DeFinis

Fred DeFinis
President

/enc.

110 Broad Street, Boston, Massachusetts 02110 Telephone: (617) 742-2400 Fax: (617) 350 6260

Mar 16, 92 14:25 No.004 P.02

Hresko Assoc/EcoHealth TEL No.617-350-6260

MITEARREST®

INSECTICIDAL BEDDING FOR RODENTS



FOR HOME PET USE

EPA Reg. No. 56783-2 EPA Est. No. 5693 MA-1
Permethrin impregnated cotton bedding to
control mite infestations on laboratory rodents.

ACTIVE INGREDIENTS:

*1 permethrin 7.4%

INERT INGREDIENTS 92.6%

Total 100.0%

*(3-phenoxyphenyl)methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)-2,2-dimethyl cyclopropane-carboxylate

*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

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IF IN EYES - Flush eyes with plenty of water. Call a physician if irritation persists.

See additional precautionary statements.

DIRECTIONS FOR USE

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APPLICATION INSTRUCTIONS

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STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage or disposal. Unused or soiled MITEARREST bedding is biodegradable and may be disposed of with other bedding (such as wood chips, sawdust, etc.) or refuse. Soiled MITEARREST bedding may be autoclaved or incinerated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to skin may cause dermal irritation or tingling. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

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NOTES

This product contains a pyrethroid insecticide which the caged animal may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using this product.

U.S. Patent No. 4,662,104

EcoHealth, Inc., (617) 742-2400
110 Broad Street, Boston, MA 02110

Net weight .5 oz.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 10 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Registration of the Product Mite Arrest Insecticidal
Bedding for Laboratory Rodents and for use by
Homeowners

TO: Theresa LeMaster/George LaRocca, PM-13
Registration Division (H7505C)

FROM: Flora Chow, Chemical Manager *Flora Chow 4 Feb 92*
Reregistration Section
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: William Burnam, Acting Chief *WBK for*
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

HED Project No.: 2-0658
Caswell No.: 652BB
Action: 305 Technical label

Please find, attached to this memo, the TB-I review of the label change with respect to the registration of the product Mite Arrest.

TB-I is recommending that OREB evaluate the potential inhalation exposure from the use and storage of this product. I am issuing an HED intra-bean to OREB requesting such a review; the OREB review will be forwarded to you separately.



Printed on Recycled Paper

21/0/92

6-2DP

12/5/91

DP BARCODE: D171969

CASE: 027678
SUBMISSION: S407829

DATA PACKAGE RECORD
BEAN SHEET

DATE: 12/04/91
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REGISTRATION
CHEMICALS: 109701 ~~Permethrin~~

ACTION: 305 TECH-LBL REV AMND DATA RE

07.4000%

ID#: 056783-00002 MITE ARREST
COMPANY: 056783 ECOHEALTH, INC.
PRODUCT MANAGER: 13 GEORGE LARocca
PM TEAM REVIEWER: THERESA LEMASTER
RECEIVED DATE: 11/22/91 DUE OUT DATE: 02/20/92

703-305-6100 ROOM: CM2 202
703-305-5418 ROOM: CM2 204

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 171969 EXPEDITE: N DATE SENT: 12/04/91 DATE RET.: / /

CHEMICAL: 109701 Permethrin

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 01/18/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT
IV : HED	/	/	/	/
BRAN: SACB	/	/	/	/
SECT: RS	/	/	/	/
REVR :	/	/	/	/
CONTR:	/	/	/	/

*** DATA REVIEW INSTRUCTIONS ***

ATTN: FLORA ~~HOW~~ 305 - 7398

PLEASE COMMENT ON PROPOSED LABEL AMENDMENT TO INCLUDE "HOMEOWNER" USE OF THIS PRODUCT.

LAST HED REVIEW (APR 19, 1990 - COPY ENCLOSED) WAS MADE IN REFERENCE TO LABEL WHICH LIMITED USE OF THIS PRODUCT TO "COMMERCIAL/VETERINARY USE ONLY" (COPY ENCLOSED).

*** ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION ***

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

John Tree
→ Marc Dow 305-3533 → Spm 1/Down 3/16 → will check to see who reviews it + call back today as to normal.

*Since Q**
if exp signif. → risk calculated in SACB → PM
if exp negli → no risk calc. → PM

IB is concerned w/ inhalation exposure, since storage would be in room.

Non Chan



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 23 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: EPA Id. No.: 056783-00002. Permethrin:
Registration of the product Mite Arrest
Insecticidal Bedding for Laboratory Rodents and
for use by homeowners.

TOX CHEM No.: 652BB
PC No.: 109701
TOX PROJECT No.: IN-0305
HED PROJECT No.: 2-0658
Submission No.: S407829

FROM: John Doherty *John Doherty* 1/23/92
Section IV, Toxicology Branch I
Health Effects Division (H7509C)

TO: Flora Chow, Ph.D.
Chemical Manager
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Marion Copley, DVM, Section Head *Marion Copley* 1/23/92
Section IV, Toxicology Branch I
Health Effects Division (H7509C)

I. CONCLUSION

Toxicology Branch considers that the toxicity data requirements necessary for the registration of this product for either laboratory or homeowner use have been met and has no objections to the proposed registrations. The use of the product, however should be evaluated by Occupational and Residential Exposure Branch to determine the inhalation exposure resulting from the use and storage of this product.

II. Action Requested

Ecohealth, Inc. has responded to the request for a specific label change made previously by Toxicology Branch (Hed Project No. 0-0693, memo dated April 19, 1990). In addition the company is now requesting that their product Mite Arrest be used



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by homeowners to control mites in pet rodent cages.

III. Toxicology Branch Comments

1. The registrant has revised the product label to include the precaution to researchers that the product contains a pyrethroid insecticide and that the possible effects of the presence of this insecticide should be considered before using the product.

2. The proposed use of this product should be reviewed by the Occupational and Residential Exposure Branch to determine the exposure resulting from the use and storage of this product in animal care facilities to individuals involved with animal care and to pet owners who may use this product in homes.

Although frequent air changes are a GLP requirement, some animal rooms have many animal cages within and each of these may have the product. Significant quantities of unused product may also be stored in the animal rooms. Thus the animal handlers and researchers may be exposed to significant quantities of permethrin. A homeowner may keep a pet rodent in a room with less frequent air changes and the product in the animal cage and in the storage package may volatilize about the room. The pet owner may spend long hours in the same room especially if the room is a bedroom.

3. A copy of the Free Standing Toxicity Profile for PERmethrin is attached.

FREE STANDING TOXICITY SUMMARY - PERMETHRIN

Toxicity Data Base: Chemical: Permethrin Data provided jointly from the FMC and ICI Corporations, the Burroughs-Wellcome Co and/or the US Army.

Tox Chem Number: 652BB
PC Number: 109701

Edition: October 22, 1991

Series.	Study Type	Study Available	Comment on study or significant finding ²	Document Number ³
81-1.	Acute oral - rats	A	Tox. Cat. III-IV	1570
81-2.	Acute Dermal - rabbits	A	Tox. Cat. IV	1570
81-3.	Acute inhalation - rats	A	Tox. Cat. IV	5/10/76
81-4.	Primary eye - rabbits	A	Tox. Cat. IV	1570
81-5.	Primary dermal - rabbits	A	Tox. Cat. IV	1570
81-6.	Dermal sensitization - guinea pig	A	Not a sensitizer (U.S.Army study).	7624
81-7.	Delayed neurotoxicity - hen	No	Not applicable	
81-8.	Special neurotoxicity - rat	No	Requirement pending. See also 82-7.	
82-1a.	Subchronic oral - rodent	3	NOEL/LEL = 100/500 ppm. <u>Liver effects.</u> NOEL = 20/100 ppm. <u>Liver effects.</u> NOEL/LEL = 20/100 ppm. <u>Liver effects.</u>	
82-1b.	Subchronic oral - nonrodent	A	NOEL/LEL = 50/364 mg/kg/day (capsule). <u>CNS</u> activity, <u>liver</u> and <u>body weight</u> effects.	
82-2.	21-day dermal	A	NOEL = 1.0 gm/kg/day (HDT). U.S. Army study.	1570
82-3.	90-day dermal	No		

82-4. 90-day inhalation - guinea pig	S	NOEL > 500 ug/l/day (HDT)	1570
90-day inhalation - dogs	S	NOEL > 500 ug/l/day (HDT)	
90-day inhalation - rat	S	NOEL/LEL = 250/500 ug/l/day. Tremors, convulsions, liver effects. All are U.S. Army studies.	
82-5. 90-day neurotoxicity - hen	No	Not applicable.	
82-6			
82-7. Neurotoxicity screen rats Special study to assess for particular pyrethroid neurotoxicity. Note: new Guidelines require additional study types.	S	NOEL/LEL 100/200 mg/kg/day. Increased irritability. Possible morphological changes at 400 mg/kg/day. No morphological lesions at 600 ppm (21 days feeding). NOEL < 4000 ppm for tremors, deaths at 9000 ppm.	5946 8163
83-1a. Chronic feeding - rat		See 83-5.	
83-1b. Chronic feeding - nonrodent	2	NOEL/LEL = 5/100 mg/kg/day (capsule). <u>Liver effects</u> . NOEL > 250 mg/kg/day (HDT).	3403
82-2a. Oncogenicity - rat		See 83-5.	
82-2b. Oncogenicity - mouse [3 studies considered acceptable, one considered invalid]	A	NOEL/LEL = 100/250 ppm. <u>Liver effects</u> . NOEL/LEL = 20/500 (males) and 2500/5000 ppm (females). <u>Liver effects</u> . Positive for <u>lung</u> and <u>liver</u> tumors. NOEL ≥ 250 mg/kg/day (HDT). Considered positive for <u>lung</u> tumors at 250 mg/kg/day.	8163
83-3a. Developmental toxicity - rat	A	NOEL/LEL = 50/150 mg/kg/day for both maternal and developmental toxicity (decreased fetal weight).	8344

83-3b. Developmental toxicity - rabbit	A	Maternal toxicity LEL < 600 mg/kg/day (equivocal body weight gain). NOEL/LEL for developmental toxicity 600/1200 mg/kg/day.	8344
83-4. Multi generation reproduction - rat	2	NOEL < 500 ppm. <u>Liver effects</u> in pups. Body tremors in parents at 1000 and 2500 ppm and in pups at 2500 ppm. NOEL > 180 mg/kg/day (HDT).	8163
83-5. Combined chronic/onco - rat	3	NOEL < 500 ppm. <u>Liver effects</u> . NOEL/LEL = 20/100 ppm. <u>Liver effects</u> . Equivocal for lung adenomas. NOEL/LEL = 10/50 mg/kg/day. <u>Liver effects</u> .	8163
84-2. Gene mutation	A	Ames test: Not mutagenic	
84-2. Chromosome aberration	No		
84-2. Other mechanism genetic toxicity.	No	Unscheduled DNA synthesis: Not mutagenic	8761
85-1. Metabolism - rats and dogs.	A	Several studies define absorption, excretion and retention of labelled permethrin.	1660 7524
85-2. Domestic animal safety		See formulations.	
85-3. Dermal Absorption - rabbits	S	[U.S. Army study indicates 30-70% absorption.]	
85-. Nerve function/operant behavior	No	Requirement pending	

A = Acceptable study satisfies the data requirement. S = a SUPPLEMENTARY study containing useful information is available but additional data are required. Number = more than one ACCEPTABLE study containing useful information has been presented. No = no acceptable or useful study has been provided.

Consult DER for additional details. Only significant toxicity at the LEL is presented.

The document number for the DER is given but in some cases when no document number is available the date of the review is given. If no date or

document number, consult the one liners for further study identification.

Special Toxicology Issues and Problems.

1. Labelling. There are no specific labelling and precautionary statements required based on the toxicity of technical permethrin. The label signal word and precautionary statements should be governed by the toxicity studies with the formulations.

2. Carcinogenicity.

The HED Peer Review Committee classified permethrin (as of September 18, 1989) as a Group C carcinogen (possible human carcinogen) and recommended that quantitative risk assessments be performed based on the FMC mouse study using the dose-related increase in combined lung adenomas and/or carcinomas observed in females.

The Q_1^* based on the FMC mouse study for lung and liver tumors is 1.84×10^{-2} (mg/kg/day).

3. RfD.

The RfD approved by the Agency RfD Committee is 0.05 mg/kg/day based on the FMC 2-year rat feeding study with a NOEL of 5 mg/kg/day and a safety factor of 100.

4. Non carcinogenic risk assessment.

There are no other specific toxicity endpoints besides carcinogenicity and RfD as indicated above.

5. Mutagenicity/genetic toxicity comments.

The mutagenicity/genetic toxicity data base is considered incomplete and is being revised and updated.

6. Dermal penetration.

The U.S. Army has submitted a study which indicates 30 - 70% of permethrin may be absorbed through rabbit skin. This study is considered SUPPLEMENTARY and additional data are required to better establish the rate of permethrin through the skin. According to Robert Zendzian, pharmacologist HED, the dermal penetration factor of 3 to 7% is currently recommended for estimating human absorption of permethrin. This is based on human skin being about 1/10 as permeable as rabbit skin.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ECOHEALTH, INC.
33 MOUNT VERNON ST.
BOSTON, MA 02108

110 Broad

02110

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/13/92. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

You provided fewer than the required three complete copies of submitted data. In the future, be sure to submit the full number of required copies.

Rejected study [01] :

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

mailed 3/1/92
Study returned to registrant

305 / 414654
11 4

Per registrant address!

Advised registrant by telephone that OREB/16 are looking at inhalation

exposure → No need to resubmit dermal irritation.

ECOHEALTH, INC.

January 31, 1992

Mr. George LaRocca RM 13
Registration Division (H7505C)
Environmental Protection Agency
Crystal Mall, Building 2
Arlington, VA 22202

Subject: Mite Arrest
EPA Registration No.: 56783-2

Dear Mr. LaRocca:

At the suggestion of Theresa LeMaster, I have enclosed some dermal irritation data to support our Amendment (Application #138534) currently pending. Please forward this to Ms. LeMaster so that she can combine it with our application.

Rejected (phi)

Thank you for your help.

Sincerely,



Fred DeFinis
President

/enc.

ECOHEALTH, INC.

November 12, 1991

Mr. George LaRocca, PM #13
Registration Division (H7505C)
Environmental Protection Agency
Crystal Mall, Bldg. 2
Arlington, VA 22202

Subject: **MITEARREST**
EPA Registration No.: 56783-2

Dear Mr. LaRocca:

As requested in the October 30, 1991 letter from Edith Minor (enclosed) I am sending you 5 copies of draft labeling to support our request for amendment. I have also re-submitted the entire package for your review.

In order to avoid further confusion, I will call you to be sure that our package is complete and meets your requirements.

Thank you for your help.

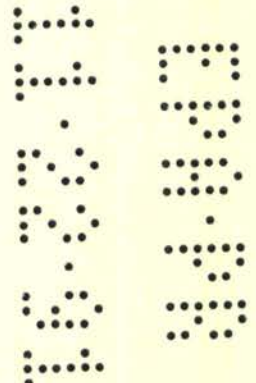
Sincerely,



Fred DeFinis
President

/enc.

Certified Mail
Return Receipt No.: P 655 440 080



MITEARRESTTM

INSECTICIDAL BEDDING FOR LABORATORY RODENTS



For Laboratory, Commercial, Veterinary or
Home Pet Use Only

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*Cis/Trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

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affected areas with plenty of soap and water.

IF IN EYES - Flush eyes with plenty of water. Call a physi-
cian if irritation persists.

See additional precautionary statements

DIRECTIONS FOR USE

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manner inconsistent with its labeling.

APPLICATION INSTRUCTIONS

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treated. Use 2-3 MITEARREST balls per week for each
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Replace soiled MITEARREST bedding; it is recommended
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vent reinfestation.

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ings, etc.) or refuse. Soiled MITEARREST bedding may be
autoclaved or incinerated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to
skin may cause dermal irritation or tingling. Wash thor-
oughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contami-
nate water by disposal.

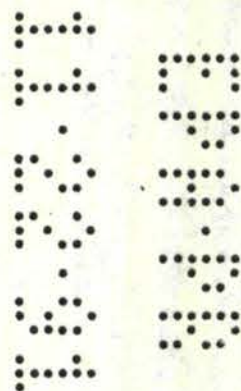
NOTE:

This product contains a pyrethroid insecticide which the
caged animal may ingest or come into dermal contact
with. Researchers should consider the possible effects of
contact with this insecticide before using this product.

U.S. Patent No. 4,662,104

EcoHealth, Inc., (617) 742-2400
110 Broad Street, Boston, MA 02110

*Superseded
by labeling
Submitted / Rev'd
3/19/92*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 30, 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis:

You were recently sent an acceptance letter for registration of your product "Mite Arrest", application number 138534, dated October 14, 1991. That acceptance letter was based on a preliminary screen for completeness.

After further review of your request by Mr. George LaRocca, Product Manager, Team 13, your request was found to be deficient and is being returned to you.

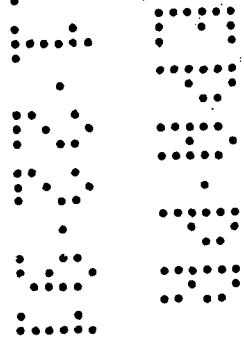
You did not submit five copies of draft labeling. No further action on your request can be taken until you bring it into compliance with Agency regulations.

If you need additional information or have any questions, please contact Mr. LaRocca on (703-557-2400).

Sincerely,

Edith Minor

Edith Minor, Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)



TO FILE ROOM _____

TO PRODUCT MANAGER 13

DATE: 11-26-91

FAST - TRACK ACTION

This action has been determined to be a fast-track action by FEPS and must be entered in the PRATS using one of the following codes:

160 - Application for "me-to" registration

170 - Application for registration - old chemical - "Me-too" with additional use.

HED 300 - Amendment - label revision - administrative (no data required).

HED 305 - Amendment - label revision - data required does not need HED/EFED review.

310 - Amendment - added "me-too" Use - no HED/EFED review needed.

345 - Formula change - no HED/EFED review required.

11/25/91

~~ALEXANDER KOVEL~~
ECOHEALTH, INC.
33 MT. VERNON STREET
BOSTON MA 02108

Product Name: MITE ARREST
Company Name: ECOHEALTH, INC.
Application No.: 138534
EPA Reg. No.: 56783-2
EPA Receipt Date: 11/22/91

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact George LaRocca, Product Manager 13, at (703)-557-2400.

Sincerely,

EJH
Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)

ECOHEALTH, INC.

October 15, 1991

Mr. George LaRocca, PM #13
Registration Division (H7505C)
Environmental Protection Agency
Crystal Mall, Bldg. 2
Arlington, VA 22202

Subject: **Mite Arrest**
EPA Registration No.: 56783-2

Dear Mr. LaRocca:

Enclosed please find an application for label amendment for the above referenced product and if necessary, authorization to access Fairfield American Corporation's data.

Please feel free to contact me if additional information or materials are necessary.

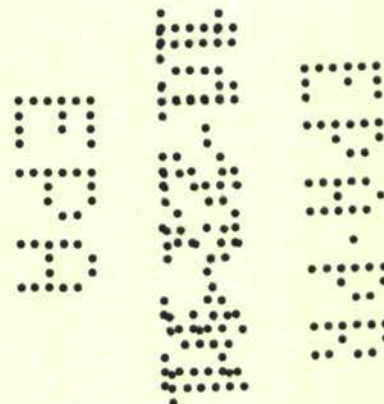
Thank you for your attention to this matter.

Sincerely,



Fred DeFinis
President

/enc.





United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Application for Pesticide: ☐ Registration
☒ Amendment

OPP Identifier Number

138534

Section I

1. Company/Product Number 56783-2	2. Date August 26, 1991	3. Product Manager George LaRocca	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
--------------------------------------	----------------------------	--------------------------------------	---

5. Name and Address of Applicant (Include ZIP Code)

EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

☐ Check if this is a new address

6. Product Name

MITE ARREST

Section II - Amendment Information

1. Subject

☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☒ Other (explain below)

Date of Letter

The Addition of a site:

"For Home Pet Use"

Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit package wgt No. per container	Water-Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package weight No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container .5 oz. .5 lb. 2.5 lb.		
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On material accompanying product		6. Manner in Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other (Specify) <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name

Fred DeFinis

Title

President

Telephone No. (Include Area Code)

617-742-2400

6. Date Application Received (Stamp)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title

PRESIDENT

4. Typed Name

Fred DeFinis

5. Date Signed

10-14-91

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

All Data For Which Claims of Confidentiality Are Asserted Must Be Submitted, Bound Separately and Clearly Marked As Such

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
 2. **Date** - Fill in the appropriate date.
 3. **Product Manager** - If known, fill in the name and number of the Product Manager.
 4. **Proposed Classification** - Specify the proposed classification for this product.
 5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.
- An applicant Not residing in the United States must have an authorized agent residing in the United States to act for

them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

MITEARREST®

INSECTICIDAL BEDDING FOR LABORATORY RODENTS



For Laboratory, Commercial or Veterinary Use Only

EPA Reg. No. 56783-2 EPA Est. No. 5693 MA 1
Permethrin impregnated cotton bedding to
control mite infestations on laboratory rodents.

ACTIVE INGREDIENTS:

+* permethrin.....7.4%

INERT INGREDIENTS:.....92.6%

Total 100.0%

phenoxyphenyl methyl (+/-) cis/trans 3-(2-chloroethenyl)-2,2-dimethyl cyclopropane-carboxylate

*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Statement of Practical Treatment

IF SWALLOWED - Contact a physician or Poison Control Center immediately.

IF ON SKIN - Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES - Flush eyes with plenty of water. Call a physician if irritation persists.

See additional precautionary statements

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

APPLICATION INSTRUCTIONS

Place MITEARREST bedding directly in rodent cage to be treated. Use 2-3 MITEARREST balls per week for each rodent. Avoid wetting the MITEARREST bedding; to prevent cage flooding, care should be taken to place MITEARREST bedding away from the water bottle spout. Replace soiled MITEARREST bedding; it is recommended that fresh MITEARREST bedding be added weekly, at the time when other bedding is changed. Continue using the product for four to six weeks, or until mites or their eggs are no longer present in the fur of rodent. As mites are not affected by this treatment, extended use of the product (until all eggs have hatched or are no longer present) will provide greater long-term control and prevent reinfestation.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage or disposal. Unused or soiled MITEARREST bedding is biodegradable and may be disposed of with other bedding (such as wood chips, shavings, etc.) or refuse. Soiled MITEARREST bedding may be autoclaved or incinerated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to skin may cause dermal irritation or tingling. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contaminate water by disposal.

NOTE:

This product contains a pyrethroid insecticide which a caged animal may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using this product.

U.S. Patent No. 4,662,104

EcoHealth, Inc., 62 742-2400
110 Broad Street, Boston, MA 02110

NOT REVIEWED

In accordance with PR Notice 82-2.
Based on draft labelling dated 7/18/90

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460	EPA REGISTRATION NO. 56783-2	DATE OF ISSUANCE JUL 18 1990
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	TERM OF ISSUANCE Until Reregistration	
NAME OF PESTICIDE PRODUCT Mite Arrest		
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)		
<div style="border: 1px solid black; padding: 10px; min-height: 150px;"> <div style="position: relative; height: 100%;"> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; border: 1px solid black;"></div> </div> </div>		
<p>NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.</p> <p>A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.</p> <p>Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p style="text-align: center;">This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data. 2. Make the labeling changes listed below before you release the product for shipment: <ol style="list-style-type: none"> a. Add the phrase, "EPA Registration No. 56783-2. " b. Under the Storage and Disposal Statement delete the word "safely". Words or phrases as to the safety of a pesticide are not acceptable. c. Revise the front panel user statement to read: For Commercial/Veterinary Use Only 		
<input checked="" type="checkbox"/> ATTACHMENT IS APPLICABLE		
SIGNATURE OF APPROVING OFFICIAL		DATE
		July 18, 1990

- d. Since laboratory rodents are used for various "research" purposes, we suggest you add the following statement under the heading **Note:**

This product contains a pyrethroid insecticide which the caged animals may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using this product.

3. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

MITE ARREST

EPA Reg. No. 56783-E

EPA Est. No. 5693 MA 1

INSECTICIDAL BEDDING FOR LABORATORY RODENTS

Permethrin impregnated cotton bedding to control mite infestations on laboratory rodents.

Intended for Commercial/Veterinary Use Only

ACTIVE INGREDIENTS:

+* permethrin.....7.4%

INERT INGREDIENTS:.....92.6%

Total 100.0%

+(3-phenoxyphenyl methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

Contents:

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF SWALLOWED - Contact a physician or Poison Control Center immediately.

IF ON SKIN - Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES - Flush eyes with plenty of water. Call a physician if irritation persists.

See additional precautionary statements

EcoHealth, Inc., 110 Broad Street, Boston, MA 02110

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Application instructions:

Place treated cotton directly in rodent cage to be treated. Use about 3 cotton balls or 3 inches of cotton for each rodent in the cage. Avoid wetting the cotton; to prevent cage flooding, care should be taken to place cotton away from the water bottle spout. Replace soiled cotton; it is recommended that fresh cotton be added weekly, at the time when other bedding is changed. Continue using the product for four to six weeks, or until mites or their eggs are no longer present in the fur of rodent. As mite eggs are not affected by this treatment, extended use of the product (until eggs are no longer present) will provide greater long-term control and prevent reinfestation.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Unused and soiled cotton is biodegradable and may be safely disposed of with other bedding (such as wood chips, shavings, etc.) or refuse. Soiled cotton may be autoclaved or incinerated.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Chronic exposure to skin may cause dermal irritation or tingling. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contaminate water by disposal.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 18 1990

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

56783-2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

APR 19 1990

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File # 56783-E. Permethrin: Registration of a new use pattern and the product Mite Arrest.

TOX CHEM No.: 652BB
TOX PROJECT No.: 0-0693
Record No.: 259013

FROM: John Doherty *John Doherty 3/22/90*
Section I, Toxicology Branch I (IRS)
Health Effects Division (H7509C)

TO: George LaRocca
Product Manager #15
Registration Division (H7505C)

THROUGH: Roger Gardner *Roger Gardner 4/10/90*
Acting Section Head
Section I, Toxicology Branch I (IRS)
Health Effects Division (H7509C)


Background

The EcoHealth Corporation is seeking to register their product Mite Arrest (EPA File Symbol 56783-E) which consists of cotton impregnated with permethrin and which will be placed in laboratory animal cages to control mites. This product is the same as the product Tick Buster which was previously reviewed by Toxicology Branch (refer to J. Doherty review dated February 25, 1987). No new toxicity data were submitted. Thus, Toxicology Branch need only to address the new use of this formulation.

Toxicology Branch Comments

Toxicology Branch has no objections regarding the registration of this product.

Note: Toxicology Branch suggests that the following note or a similar note be added to the label. "This product contains a pyrethroid insecticide which the caged animals may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using this product".

652BB  United States Environmental Protection Agency Office of Pesticide Programs Washington, DC 20460 Data Review Record Confidential Business Information - Does not contain National Security Information (E.O. 12065)		Pack Number <div style="font-size: 1.5em; font-family: cursive;">0-0693</div>	Date Received <div style="font-size: 1.5em; font-family: cursive;">2/15/90</div>			
1. Product Name <div style="font-size: 1.2em; font-family: cursive;">Mite Arrest</div>		Chemical Name <div style="font-size: 1.2em; font-family: cursive;">Permethrin</div>				
2. Identifying Number <div style="font-size: 1.2em; font-family: cursive;">56783-E</div>	3. Record Number <div style="font-size: 1.2em; font-family: cursive;">259013</div>	4. Action Code <div style="font-size: 1.2em; font-family: cursive;">175</div>	5. MRID/ Accession Number <div style="font-size: 1.2em; font-family: cursive;">41378801</div>	6. Study Guideline or Narrative 		
7. Reference No. <div style="font-size: 1.2em; font-family: cursive;">2</div>	8. Date Rec'd (EPA) <div style="font-size: 1.2em; font-family: cursive;">2/1/90</div>	9. Prod/Review Mgr/DCI <div style="font-size: 1.2em; font-family: cursive;">LaRocca/03</div>	10. PM/RM Team No. <div style="font-size: 1.2em; font-family: cursive;">15</div>	11. Date to HED/ EFED/RD/BEAD <div style="font-size: 1.2em; font-family: cursive;">2/12/90</div>	12. Proj Return Date <div style="font-size: 1.2em; font-family: cursive;">5/12/90</div>	13. Date Returned to RD/SRRD <div style="font-size: 1.2em; font-family: cursive;">4/19/90</div>
Instructions <div style="font-size: 1.2em; font-family: cursive;"> Review for new use pattern of mite control upon lab rats similar to EPA Reg No. 56783-11 For back ground information refer to review by John Doherty dated 2/25/87, ref. label enclosed also carry efficacy data doc background information on that product is needed. </div>						
This Section Applies to Review of Studies Only						
14. Check Applicable Box <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870) </div> <div> <input type="checkbox"/> Generic Data (Reregistration) (660) <input type="checkbox"/> Product Specific Data (Reregistration) (655) </div> </div>					15. No. of Individual Studies Submitted <div style="font-size: 1.2em; font-family: cursive;">1</div>	
16. Have any of the above studies (in whole or in part) been previously submitted for review? <input type="checkbox"/> Yes (Please identify the study(ies)) <input checked="" type="checkbox"/> No					17. Related Actions <div style="font-size: 1.2em; font-family: cursive;">SRRD</div>	
18.	To	Type of Review	19. Reviews Also Sent to		20. Data Review Criteria	
HED	X	Science Analysis & Coordination	<input type="checkbox"/> SAC	<input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements	
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	<input type="checkbox"/> PL		
		Toxicology/IR	<input type="checkbox"/> TOX/IR	<input type="checkbox"/> EA		
		Dietary Exposure	<input type="checkbox"/> DEB	<input type="checkbox"/> AC		
		Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> BA		
EFED		Ecological Effects	<input type="checkbox"/> EEB		B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert	
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB			
SRRD		Special Review	<input type="checkbox"/> SR			
		Reregistration	<input type="checkbox"/> RER			
		Generic Chemical Support	<input type="checkbox"/> GSC			
RD		Insecticide-Rodenticide	<input checked="" type="checkbox"/> RER	EFF B.		
		Fungicide-Herbicide	<input type="checkbox"/>			
		Antimicrobial	<input type="checkbox"/>			
		Product Chemistry	<input type="checkbox"/> IR			
		Precautionary Labeling	<input type="checkbox"/> FH			
BEAD		Economic Analysis	<input type="checkbox"/> AM			
		Analytical Chemistry				
		Biological Analysis				
<input checked="" type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)			<input checked="" type="checkbox"/> Label Attached			


 United States Environmental Protection Agency
 Office of Pesticide Programs
 Washington, DC 20460

Data Review Record

 Confidential Business Information - Does not contain
 National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Arite Arrest

Chemical Name

Permethrin

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
56783-E	254013	ETD 175	41378301	

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
2	2/1/90	Larocca/03	15	2/12/90	5/12/90	

Instructions

Review for new use pattern - lab animals against mites
 similar to EPA Reg # 56783-1 - ref. Label enclosed.

This Section Applies to Review of Studies Only

14. Check Applicable Box	15. No. of Individual Studies Submitted
<input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870)	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31 <input type="checkbox"/> 32 <input type="checkbox"/> 33 <input type="checkbox"/> 34 <input type="checkbox"/> 35 <input type="checkbox"/> 36 <input type="checkbox"/> 37 <input type="checkbox"/> 38 <input type="checkbox"/> 39 <input type="checkbox"/> 40 <input type="checkbox"/> 41 <input type="checkbox"/> 42 <input type="checkbox"/> 43 <input type="checkbox"/> 44 <input type="checkbox"/> 45 <input type="checkbox"/> 46 <input type="checkbox"/> 47 <input type="checkbox"/> 48 <input type="checkbox"/> 49 <input type="checkbox"/> 50 <input type="checkbox"/> 51 <input type="checkbox"/> 52 <input type="checkbox"/> 53 <input type="checkbox"/> 54 <input type="checkbox"/> 55 <input type="checkbox"/> 56 <input type="checkbox"/> 57 <input type="checkbox"/> 58 <input type="checkbox"/> 59 <input type="checkbox"/> 60 <input type="checkbox"/> 61 <input type="checkbox"/> 62 <input type="checkbox"/> 63 <input type="checkbox"/> 64 <input type="checkbox"/> 65 <input type="checkbox"/> 66 <input type="checkbox"/> 67 <input type="checkbox"/> 68 <input type="checkbox"/> 69 <input type="checkbox"/> 70 <input type="checkbox"/> 71 <input type="checkbox"/> 72 <input type="checkbox"/> 73 <input type="checkbox"/> 74 <input type="checkbox"/> 75 <input type="checkbox"/> 76 <input type="checkbox"/> 77 <input type="checkbox"/> 78 <input type="checkbox"/> 79 <input type="checkbox"/> 80 <input type="checkbox"/> 81 <input type="checkbox"/> 82 <input type="checkbox"/> 83 <input type="checkbox"/> 84 <input type="checkbox"/> 85 <input type="checkbox"/> 86 <input type="checkbox"/> 87 <input type="checkbox"/> 88 <input type="checkbox"/> 89 <input type="checkbox"/> 90 <input type="checkbox"/> 91 <input type="checkbox"/> 92 <input type="checkbox"/> 93 <input type="checkbox"/> 94 <input type="checkbox"/> 95 <input type="checkbox"/> 96 <input type="checkbox"/> 97 <input type="checkbox"/> 98 <input type="checkbox"/> 99 <input type="checkbox"/> 100
<input type="checkbox"/> Generic Data (Reregistration)(660) <input type="checkbox"/> Product Specific Data (Reregistration)(655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?	17. Related Actions
<input type="checkbox"/> Yes (Please identify the study(ies)) <input checked="" type="checkbox"/> No	

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input checked="" type="checkbox"/> TOX/IR <input type="checkbox"/> EA	
		Dietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> AC	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> BA	
EFED		Ecological Effects	<input type="checkbox"/> EEB	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD	<input checked="" type="checkbox"/>	Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

PCB ACCEPT
 6-8-90

☒ Confidential Statement of Formula
 (EPA Form 8570-4) Attached (Trade Secrets)

☒ Label Attached

PRODUCT PERFORMANCE REVIEW

PM: 12

OUT: 6-8-90

Mite Arrest
56783-E
Ecohealth, Inc.
Boston, MA

IN: 2-12-90
DUE: 5-12-90
AC: 175
RN: 259013

FORMULATION

Active Ingredient:
permethrin 7.4%

The formulation is permethrin impregnated cotton balls (used for bedding material for laboratory rodents).

USES AND LABELING

This product has been designed to control mite infestations on laboratory rodents. Directions for use are as follows:

Treated cotton balls are placed directly into rodent cages. Recommended use rate is 3 cotton balls or 3 inches of cotton for each rodent in the cage. Avoid wetting the cotton; to prevent cage flooding, care should be taken to place cotton away from the water bottle spout. Soiled cotton should be replaced and fresh cotton added weekly when other bedding is changed. The product is to be used for four to six weeks or until mites or their eggs are no longer present in the fur of the rodents. Mite eggs are not controlled by this treatment, therefore, greater long-term control and prevention of reinfestations can best be achieved by extending treatment until eggs are no longer present in the fur of the rodents.

DATA

Thomas Mather, EcoHealth employee and research scientist for Harvard School of Public Health and Niels Lausen, Animal Resources Center at Harvard Medical School, performed the efficacy tests used to support the registration of this product.

Efficacy of this product in controlling the following fur mites was determined: Myobia musculi, Radfordia affinis and Mycoptes musculus (Acari: Myobiidae). The authors indicate that these mites can infest whole colonies of laboratory rodents and adversely affect the health of the rodents (and confound the results of the laboratory tests). Mite infestations often result in hypersensitivity-induced skin lesions which can promote secondary bacterial infection. Infested mice may exhibit alterations to their normal immune status and epidermis and ha2r

regrowth may be affected in some strains. Severe or prolonged infestation can result in permanent disfigurement due to scratching. Controlling these mites in laboratory animals has been difficult due to toxicity of miticidal agents to the animals and handlers and lack of long-term control. Permethrin had shown potential as a miticidal agent because when applied directly to mice or mixed in powder form with wood shaving, it provided satisfactory short-term reductions in mite infestations without producing any noticeable effect to treated mice, including histopathologic findings in liver, lung and kidney.

The authors also summarized their success with the similar product Damminix for controlling Ixodes dammini ticks in natural infestations of the white footed deer mouse. The authors attributed part of the success of the Damminix product to the high degree of acceptability of the cotton as nesting material for the mice. They noted the affinity the mice had for the treated cotton in laboratory tests and determined that this would also be a good technique for controlling mites in laboratory rodents.

Methods

The study was conducted on a transgenic mouse colony (all backcrossed to CD-1 or Balb/C mice) holding about 20 strains and approximately 1200 mice total. The colony was 24 months old and infested with fur mites. Mice were caged in standard shoebox cages, each holding 1 - 5 mice per cage. All treatment cages were kept in one room on stainless steel racks. Animals were fed and watered ad libitum and the wood chip bedding lining the bottom of the cages was changed once weekly.

Mice were examined for mite infestation using the scotch tape impression method with microscopic interpretation. This method was chosen because it permits adequate sampling of the animal pelage without the need for skin scrapings under anesthesia or post-mortem inspections. The Harvard medical laboratories have found this system to be as reliable for determining mite infestations as scrapings.

Eight cages from each rack were randomly selected and marked. The head and back of 50% of the mice (usually 2) from each of the marked cages were examined for mite and mite egg infestation using the scotch tape impression method. The mice were examined both before and after one, two and four weeks of treatment.

Standard cotton balls (about 2 cm in diameter) were impregnated with permethrin as follows: the cotton balls were soaked in aqueous solutions of permethrin, the volume of liquid used was sufficient to just saturate the cotton mass (about 10 times the weight of the cotton). Three treatment levels of permethrin 0.3,

5.0 and 7.4% active permethrin (w/w) per dry cotton ball (actual concentration of permethrin will depend upon type of cotton used) and an untreated check were used in this study. After soaking, the cotton balls were air dried. The concentration of permethrin in the various batches of cotton was confirmed by examination of acetone extracts from treated cotton balls using reverse phase High Pressure Liquid Chromatography, employing a C18 column with the sample diluted in 80% methanol in water. Effluent from the column was monitored at 280 nm, and the area of each peak was calculated by computer.

Following the initial examination of the mice for mite counts, the technologist in charge of care of the colony was provided with the treated and untreated cotton balls and instructed to give all of the cages on a rack cotton containing the same concentration of permethrin throughout the study. Each cage on a rack received about 5 cotton balls per mouse up to a total of 25 cotton balls per cage. Fresh cotton was provided weekly to all cages at the same time bedding was changed. All sampling, examinations and evaluations were performed by the authors without knowledge of the treatment given. Only the technologist knew the level of treatment for each rack.

Results

The initial sampling of the colony indicated that 88% (n = 76) were infested with mite eggs awhile 40% were infested with nymphal or adult mites. Totally, 90% of the mice were infested with either eggs or mites. Mites identified included M.muscali, R.affinis, and M.musculus, however, separate counts of the species were not provided. A heavy infestation was characterized by more than 5 adult or nymphal mites or more than 15 eggs per slide and occurred on about 20% of the mice. Only 10% of the mice with heavy infestations exhibited severe symptoms, including lesions. The authors indicated that mice readily accepted the treated cotton and used it to construct nests.

A summary of the experiment follows:

TABLE 1.

Summary of Actual Counts of Mite Eggs, Nymphs and Adults Infesting Mice Treated with Cotton Impregnated with Various Concentrations of Permethrin.

RACK #	TREATMENT	MITE STAGE	PROPORTION OF MICE INFESTED ON			
			WEEK 0	WEEK 1	WEEK 2	WEEK 4
I	5%	EGGS	11/16	9/15	3/15	5/15
		MITES	5/16	1/15	1/15	0/15
II	7.4%	EGGS	11/15	11/16	2/15	3/15
		MITES	5/15	0/16	0/15	0/15
III	0.5%	EGGS	16/16	15/15	7/15	8/15
		MITES	10/16	1/15	7/15	2/15
IV	CONTROL	EGGS	15/15	14/15	10/13	12/13
		MITES	6/15	13/15	9/13	4/13
V	7.4%	EGGS	14/14	14/14	4/11	6/12
		MITES	4/14	1/14	0/11	0/12

TABLE 2.

Percent Control of Mite Eggs, Nymphs and Adults Infesting Mice Treated with Cotton Impregnated with Various Concentrations of Permethrin.

RACK #	TREATMENT	MITE STAGE	PERCENT CONTROL/WEEKS POST-TREATMENT		
			WEEK 1	WEEK 2	WEEK 4
I	5%	EGGS	40	80	67
		MITES	93	93	100
II	7.4%	EGGS	31	87	80
		MITES	100	100	100
III	0.5%	EGGS	0	54	47
		MITES	93	54	87
V	7.4%	EGGS	0	64	50
		MITES	93	100	100

DISCUSSION

All permethrin treatments provided good to excellent control of nymph and adult mites after 4 weeks of treatment. Mice receiving the 5.0% and 7.4% a.i. permethrin treatments were adult and nymph free after 4 weeks of treatment. There was a sharp decline in nymph and adult numbers in all permethrin treatments one week after initial treatment. Egg counts declined after 2 weeks of treatment in all permethrin treatments. Eggs were detected in all treatments 4 weeks after the initial treatment, however, the authors indicated that some of the eggs were empty.

The authors provided the following discussion of the results:

"In our study, mice were mite-free in both the 5% and 7.4% treatments after four weeks of applying treated nest material, although a few embryonated and empty mite eggs remained on the fur of some mice. We observed that eggs present prior to the initial treatment and on control mice could be distributed anywhere along the entire hair shaft, whereas, most eggs found on treated mice later during the study were usually nearer the distal end of the hair. Eggs observed close to the base of the hair shaft were more likely embryonated, while eggs observed near the distal end were most often empty. Additionally, after three and four weeks of treatment, eggs were found on fewer of the mice treated with 5% and 7.4% cotton than at the beginning of the study. Taken together, these observations suggest that new oviposition ceased near the time of first application. Given the 23 day natural life cycle of these mite, the fact that egg hatching is nonsynchronous and continuous, and that permethrin treatment is not ovicidal, a minimum of four to five weeks of treatment of the entire colony would appear necessary to prevent reinfestation. Furthermore, extended use of treated nest material can prevent new infestations in settings where mice are continually introduced from outside the colony, or where contamination from feral animals is a possibility."

The authors have provided some good information on the life cycle of the mites and egg placement before and after permethrin treatment. The data indicate that adult and nymphal stage mites are controlled after four weeks of continuous application of the 5.0% or 7.4% a.i. treatments. A further test of the effectiveness of this product would be to continue sampling the mice after discontinuing treatment after week 4 to determine if any of the embryonated eggs were viable and if reinfestation occurred.

This treatment would probably not be permissible for laboratory rodents intended for use in insecticide testing.

- 6 -

CONCLUSIONS

The data are acceptable to support the label claims.

Pat Bagley
PM 17
Efficacy Review



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

138108

Application for Pesticide: ☒ Registration
☐ Amendment

Section I

1. Company/Product Number
56783-E

2. Date

3. Product Manager
George LaRocca

4. Proposed Classification
☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

ECOHEALTH, INC.
110 BROAD STREET
BOSTON, MA 02110

☒ Check if this is a new address

6. Product Name
MITE ARREST

Section II - Amendment Information

1. Subject

☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☐ Other (explain below)

Date of Letter

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging ☐ Yes ☒ No

Unit Packaging ☐ Yes ☒ No

If "Yes," Unit package wgt No. per container

Water-Soluble Packaging ☐ Yes ☒ No

If "Yes," Package weight No. per container

2. Type of Container

☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)

3. Location of Net Contents Information ☐ Label ☒ Container

4. Size(s) of Retail Container
UNDETERMINED

5. Location of Label Directions ☒ On Label ☐ On material accompanying product

6. Manner in Which Label Is Affixed To Product ☐ Lithograph ☒ Paper glued ☐ Other (Specify) ☐ Stenciled

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name THOMAS MATHER - ECOHEALTH, INC.
110 BROAD STREET
BOSTON, MA 02110

Title Chief Research Scientist

Telephone No. (Include Area Code) (617) 731-6470 (ex. 107)

6. Date Application Received (Stamped)

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
Thomas N. Mather

3. Title
Chief Research Scientist

4. Typed Name
THOMAS MATHER

5. Date Signed
1/9/90

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

ECOHEALTH, INC.

The Makers of **DAMMINIX**

January 19, 1990

Mr. George LaRocca, PM #15
Registration Division (H7505C)
Insecticide-Rodenticide Branch
Environmental Protection Agency
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Mite Arrest, EPA File Symbol 56783-E
Application for Pesticide Registration, OPP ID #138108

Dear Mr. LaRocca:

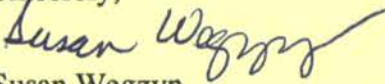
Enclosed please find registration information for the above-referenced product. Please take note that in the midst of preparing this application, EcoHealth, Inc. moved its primary location of business from 33 Mount Vernon Street, Boston, MA to 110 Broad Street, Boston, MA. Several papers within this package of registration materials still have the former address printed on them. In the future, please submit all correspondence regarding this application to:

EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

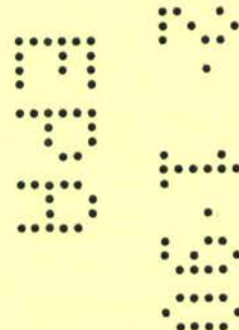
Our telephone number remains the same - (617) 742-2400.

We look forward to hearing from you soon.

Sincerely,


Susan Wegzyn
EcoHealth staff

/enc.



DATA REFERENCE MATRIX

3. APPLICANT'S NAME AND ADDRESS ECOHEALTH INC. 110 Broad Street Boston, MA 02110		4. PRODUCT NAME: MITE ARREST		1. PAGE 1 OF 3	
		5. NAME OF ACTIVE INGREDIENT(S): PERMETHRIN		2. EPA REGISTRATION NO./ FILE SYMBOL: 56783-E	
				FORMULATOR'S EXEMPTION SELECTED: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
				6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED 11/9/90	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT					10. MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER	
8a. Regulation Part 158/ Guideline Number	8b. Name of Requirement	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed	9e. Public Literature	9f. N.A. or Waiver or other (explain)	
§158.20	PRODUCT CHEMISTRY							
61-1	IDENTITY OF INGREDIENTS	X	10/20/85					00164297
61-2	STATEMENT OF COMPOSITION	X	10/20/86					00164297
61-3	DISCUSSION OF FORMATION OF IMPURITIES	X	10/20/86					00164297
62-1	PRELIMINARY ANALYSIS	X	10/20/86					00164297
62-2	CERTIFICATION OF LIMITS	X	10/20/86					00164297
62-3	ANALYTICAL METHODS FOR ENFORCEMENT OF LIMITS	X	10/20/86					00164297
63-2	COLOR	X	10/20/86					00164297
63-3	PHYSICAL STATE	X	10/20/86					00164297
63-4	ODOR	X	10/20/86					00164297
63-5	MELTING POINT						N.A.	
63-6	BOILING POINT						N.A.	
63-7	DENSITY, BULK DENSITY, OR SPECIFIC GRAVITY	X	10/20/86					00164297
63-8	SOLUBILITY						N.A.	
63-9	VAPOR PRESSURE						N.A.	
63-10	DISSOCIATION CONSTANT						N.A.	

<p align="center">DATA REFERENCE MATRIX</p>		1. PAGE 3 OF 3
		2. EPA REGISTRATION NO./ FILE SYMBOL: 56783- <u>E</u>
<p>3. APPLICANT'S NAME AND ADDRESS</p> <p align="center">ECOHEALTH INC.</p> <p align="center">110 Broad Street Boston, MA 02108</p>	4. PRODUCT NAME:	<p>FORMULATOR'S EXEMPTION SELECTED:</p> <p>YES <u>X</u> NO <u> </u></p>
	5. NAME OF ACTIVE INGREDIENT(S):	6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED
	PERMETHRIN	11/9/90

82

DATA REFERENCE MATRIX

1. PAGE 2 OF 3	
2. EPA REGISTRATION NO./ FILE SYMBOL: 56783-E	
FORMULATOR'S EXEMPTION SELECTED: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED 11/9/90	
4. PRODUCT NAME: MITE ARREST	
5. NAME OF ACTIVE INGREDIENT(S): PERMETHRIN	
3. APPLICANT'S NAME AND ADDRESS ECOHEALTH INC. 110 Broad Street Boston, MA 02110	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT				10. MRID NUMBER		
8a. Regulation Part 158/ Guideline Number	8b. Name of Requirement	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed	9e. Public Literature	9f. N.A. or Waiver or other (explain)	EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
\$158.20	PRODUCT CHEMISTRY (Continued)							
63-11	OCTANOL/WATER PARTITION COEFFICIENT						N.A.	
63-12	pH	X	10/20/86					00164297
63-13	STABILITY						N.A.	
63-14	OXIDIZING/REDUCING REACTION	X	10/20/86					00164297
63-15	FLAMMABILITY	X	10/20/86					00164297
63-16	EXPLODABILITY	X	10/20/86					00164297
63-17	STORAGE STABILITY	X	10/20/86					00164297
63-18	VISCOSITY	X	10/20/86					00164297
63-19	MISCIBILITY : ...	X	10/20/86					00164297
63-20	CORROSION CHARACTERISTICS	X	10/20/86					00164297
63-21	DIELECTRIC BREAKDOWN VOLTAGE						N.A.	

CERTIFICATION WITH RESPECT TO CITATION OF DATA

ECOHEALTH, INC.

33 Mt. Vernon Street, Boston, MA 02108

EPA FILE/SYMBOL/REG. NO. 56783-
NAME OF PRODUCT: Mite Arrest

DATE OF APPLICATION

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of an identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitted to cite that study.

3. I certify that, for each study cited in support of this application for registration that is NOT an exclusive study:

I have obtained the written permission of the original data submitted to cite the study; OR

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiation to determine which data are subject to the compensation requirements of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (CHECK ONE)

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). (ALSO SIGN THE GENERAL OFFER TO PAY STATEMENT BELOW.)

☒ Those companies who have submitted the studies which I have cited (SELECTIVE METHOD)

Thomas N. Mather
(Signature)

Thomas Mather, Chief Research Scientist
(Name & Title)

1/9/90
(Date)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Thomas N. Mather
(Signature)

Thomas Mather, Chief Research Scientist
(Name & Title)

1/9/90
(Date)

FORMULATOR'S EXEMPTION STATEMENT

(40 CFR 152.85)

ECOHEALTH INCORPORATED

33 Mt. Vernon Street, Boston, MA 02108

EPA FILE SYMBOL/REG. NO. 56783
NAME OF PRODUCT

DATE OF CSF

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):
Permethrin
- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.


(3) Indicate by checking (A) or (B) below which paragraph applies:

- X (A) An accurate Confidential Statement of Formula (CSF) (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The CSF (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Product Name	Source	Registration #
Permethrin			

<u>Thomas N. Mather</u>	Thomas Mather, Chief Research Scientist	5/9/90
(Signature)	(Name & Title)	(Date)

Product ingredient source information may be entitled to confidential treatment

FEB - 6 1990

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ECOHEALTH, INC.
33 MOUNT VERNON ST.
BOSTON, MA 02108

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/01/90. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

ECOHEALTH, INC.

The Makers of DAMMINIX

January 9, 1990

Mr. George LaRocca, PM #15
Registration Division (H7505C)
Insecticide-Rodenticide Branch
Environmental Protection Agency
Crystal Mall Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

413783-φφ

SUBJECT: Mite Arrest, EPA File Symbol 56783-E
Application for Pesticide Registration, OPP ID # 138108

Dear Mr. LaRocca:

Enclosed please find EcoHealth Inc.'s subject registration application for a pesticide containing the active ingredient permethrin. The proposed product is nearly identical to our existing registration for Damminix (EPA Reg. No. 56783-1), but incorporates a new use pattern (for use on laboratory animals against mites). As this product is identical in formulation to Damminix, we ask that you refer to the existing data in that registration file in support of the Product Chemistry data requirements. To satisfy the additional requirements for registration of this product, we are enclosing the following:

Administrative Materials:

1. Application Form (OPP ID # 138108)
2. Formulator's Exemption Statement
3. Certification with Respect to Citation of Data
4. Confidential Statement of Formula
5. Data Reference Sheet
6. Proposed product labeling (five copies)

Supporting Data:

- 413783φ1 7. Volume 1 - Product Performance Data (three copies)

Should you have any questions or require further information, please don't hesitate to call (617/731-6470).

Sincerely,

Thomas N. Mather

Thomas N. Mather, Ph.D.
Chief Research Scientist

CERTIFIED MAIL
RETURN RECEIPT NUMBER.....

Record Number _____

Reference Number _____

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFile Symbol/Reg. No. 66783-E PM 15 | 8 | Action Code _____

|10| Descriptor (Amend/Resubmissions only) _____

|5| Intrastate Call-in ☐ (Y) Yes |15| Child-resistant Packaging ☐ (C) Certification
☐ (N) No ☐ (S) Service Person

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☐ (N) Not Classified

|35| Date on Application: |04| EPA Received Date:

|0| |1| |09| |9| |0|
MO DAY YR|0| |2| |0| |1| |9| |0|
MO DAY YR

|40| Date Received by PM

| | | | | |
MO DAY YR

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission☐ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

|85| Certification Statement:

☒ (1) Yes☐ (2) Not Submitted☐ (3) Not Applicable

Reviewers Requested:

RD

PM

PL

CH

EF

DATE SENT DUE DATE DATE RETURNED

RESPONSE CODE RESPONSE DATE

|108| Status: _____

|115| FINAL Response ACTION Code _____

|120| Response

| | | | | |
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

